UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
HAMILTON, MONPLAISIR G

ART UNIT	PAPER NUMBER
2172	

DATE MAILED: 01/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

	Application No.	Applicant(s)
Office Action Summary	09/836,653	DURKALSKI, WESLEY PAUL
	Examiner	**Art Unit**
	Monplaisir G Hamilton	2172

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>09 October 2003</u>.

2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1-20</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1-20</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on <u>09 October 2003</u> is/are: a)☐ accepted or b)☒ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

        1.☐ Certified copies of the priority documents have been received.

        2.☐ Certified copies of the priority documents have been received in Application No. _____.

        3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

    a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .

4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: .

DETAILED ACTION

1.   Claims 1-20 remain for examination.

Drawings

.2. .   . . The drawings were received on 10/09/03. . These drawings are acceptable. However, ...

Formal drawings are required.

Response to Arguments

3.   Applicant's arguments filed 10/9/03 have been fully considered but they are not

persuasive.

Applicant argues: *"Microsoft Press Computer Dictionary does not teach a database.* Unlike a

document, a database typically comprises a schema, or organizational structure, not inherent in a

document. Thus, a document is not the equivalent of a database. That the two structures are different is

recognized even by Umen, which refers separately to databases and to documents. For example, col. 3,

lines 33-39 of Umen describe that *documents* can be generated on the basis of information stored within a

database, and that the *database* can be updated on the basis of information contained within the

documents. Clearly, a document and a database management system are not equivalents.   Even if a

document could be considered the equivalent of a database, Applicants respectfully point out that claims 1

and 20 do not merely recite a "database," as asserted by the Office Action. Rather, the claims recite a

"database management system." A database management system typically comprises a collection of

information organized in such a way that a computer program can quickly select desired pieces of data. A

database management system typically also comprises a means, such as software, for organizing and

managing the flow of information within one or more databases that are managed by the database management system. A database management system may include documents as part of the information it organizes, but a database management system is not the equivalent of a document. As asserted by the Office Action, Umen teaches customized documents, and does not teach a customized database. However, Applicant respectfully asserts for the reasons above that a database is not the equivalent of a document. Moreover, Umen fails to teach a database management system, as recited in the claims. Therefore, the combined teachings of Umen and Microsoft Press Computer Dictionary do not teach a customized database management system. Because the combined references do not teach or suggest all the claim limitations, claims 1 and 20 are nonobvious."

Examiner disagrees with applicant. The documents disclosed by Umen are essentially a database accessed and managed using the management interface of the drug documentation system (col 5, lines 10-20). Umen's system uses template/schema information, to organize the document/database information stored on disk. Using the template information Umen's system creates documents/databases that are in accordance with FDA, EU, Company, or other predetermined formats (col 10, lines 50-55). Although Umen does not explicitly disclose the creation of a customized database management system, documents generated by Umen are equivalent to the claimed system because they provide a mechanism to manipulate, organize and access information stored on disk (col 13, lines 60-68, col 16, lines 50-65). Examiner holds that the documents generated by Umen interface with the data stored on disk and provides management and updating functionalities (col 16, lines 50-65). Therefore, examiner maintains that the claimed invention is unpatentable.

Applicant further argues: *"Claim 1 is additionally nonobvious because Umen does not teach,*

"retrieving a set of rules associated with the anticipated use of the customized database management

system." The Office Action asserts that Umen (col. 6, line 50 - col. 7, line 15) teaches retrieving a set of

rules associated with the anticipated use of the customized database management system. Applicant

respectfully disagrees. The cited portions of Umen teach the use of "text objects" for storing items of data

related to a clinical study. Umen teaches that "text files" are files that contain information about a

particular study that might be managed within a clinical studies database. A user can enter study data into

a text file, and a user interface may be used to retrieve information from a text file and display it to a user

in a particular format. However, the cited portion of Umen does not disclose retrieving a set of rules

associated with the anticipated use of a database system. Therefore, claim 1 is nonobvious."

Examiner disagrees with applicant. Umen discloses template information provides a

mechanism for formatting the stored information according to well-known standards/rules (col

10, lines 50-55). Furthermore, Umen discloses templates/rules provide guidance for composing

text objects. Therefore depending on whether the stored data is being used for FDA or EU

purposes the management system organizes the information accordingly (col 10, lines 50-55).

Applicant is respectfully reminded that the citations given are for convenience purposes.

Applicant is responsible for comprehending the entire disclosure and not only the cited portions.

Applicant further argues: *"Umen does not teach generating a customized database*

management system according to the analyzing of an answer and rule set. The Office Action asserted that

col. 2, lines 25-68 of Umen teach analyzing a set of rules, and that col. 10, lines 45-55 disclose generating

a customized database management system according to that analysis. Applicant respectfully disagrees

with each of these assertions. Col. 2, lines 25-68 of Umen disclose handling rules, such as FDA rules, but

the teachings are limited to the handling of such rules to generate a form that adheres to the rules. The teachings do not embrace generating a *customized database management system* according to the rules. Col. 10, lines 45-55 also discloses the generation of forms that comply with FDA or other administrative rules, but does not disclose creating a *customized database management system*. As explained above, a document is not the equivalent of a database management system. Neither is a method of generating a properly formatted form the equivalent of a method of generating a customized database management system. Therefore, claims 1 and 20 are nonobvious."

Examiner disagrees with applicant. The customized database management system disclosed by applicant is no more than an interface used to access and manage the stored underlying data. Examiner holds that the generation of a document/form that adheres to stored. template/rule information is essentially equivalent to the generation of a customized database management system that adheres to FDA rules. Examiner therefore holds that the claimed invention is unpatentable.

Applicant further argues: "*4. Claims 1 and 20 are, additionally nonobvious because there is no suggestion or motivation to modify Umen or to combine Umen with Microsoft Press Computer Dictionary.* The Office Action stated that it would have been obvious to one skilled in the art to combine the document generation system of Umen with the "document" defined in MPCD at the time the invention was made. The Office Action indicated that col. 2, lines 55-56 of Umen describe a motivation for such a combination: providing a database that is in compliance with FDA clinical trials regulatory rules. First of all, the cited portions of Umen do not describe what the Office Action purports. Rather, they describe the preparation of *documents* that are complaint with *document requirements* prescribed by regulatory agencies (Umen, col. 2, lines 64-67). Second, even if Umen did describe providing a *database* that is in

compliance with FDA clinical trials regulatory rules, that would be one of the *results* of Applicants' invention, not a *motivation* to practice it. Therefore, claims 1 and 20 are nonobvious".

As disclosed by MPCD a document can be a spreadsheet, a structured document used to organize information. Umen discloses that the document generation system is able to create documents/database that include statistics tables/spreadsheets (col 6, lines 50-65). Therefore, in view of this disclosure at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the teachings of Umen such that the generated documents are used to interface with the stored data. One of ordinary skill in the art would have been motivated to do this because it would provide a system for managing information. It would also provide a system that is able to generate databases/documents according to the provided regulations/rules.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4.   Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5963967

issued to Umen et al, further in view of Microsoft Press Computer Dictionary Third Edition.

Referring to Claims 1 and 20:

Umen discloses a method for creating a customized database (document) management

system, the method comprising: providing a user with at least one question related to an

anticipated use of the customized database (document) management system (Fig 3; col 6, lines

10-25);

receiving at least one answer to the at least one question from the user (col 6, lines 10-

25);

retrieving a set of rules associated with the anticipated use of the customized database

management system (col 6, line 50-col 7, line 15);

analyzing the at least one answer and the set of rules (col 2, lines 25-68; col 10, lines 45-

55); and generating the customized database (document) management system according to the

analyzing of the at least one answer and the set of rules (col 10, lines 45-55).

Umen does not disclose the claimed "customized database".

Microsoft's Computer dictionary defines a document to be any self-contained piece of work created with an application program and, if saved on disk, given a unique filename by which it can be retrieved. Documents are generally thought of as word-processed materials only. To a computer, however, data is nothing more that a collection of characters, so a spreadsheet or a graphic is as much a document as is a letter or report. Therefore a document and the claimed customized database are equivalent.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the teachings of Umen to generate the claimed customized database/document. One of ordinary skill in the art would have been motivated to do this because it would provide a database that is in compliance with FDA clinical trials regulatory rules (col 2, lines 55-65).

Referring to Claim 2:

Umen discloses the limitation as discussed in Claim 1 above. Umen further discloses the customized database management system is a clinical trials database management system (col 4, lines 55-65).

Referring to Claim 3:

Umen discloses the limitation as discussed in Claim 1 above. Umen further discloses the anticipated use is administration of a clinical trial (col 4, lines 1-20).

Referring to Claim 4:

Umen discloses the limitation as discussed in Claim 3 above. Umen further discloses the

set of rules is derived from clinical trials regulations (col 2, lines 1-68; col 6, lines 60-65; col 10,

lines 45-60).

Referring to Claim 5:

Umen discloses the limitation as discussed in Claim 1 above. Umen further discloses the

set of rules governs the at least one answer (col 9, line 60-col 10, line 30).

Referring to Claim 6:

Umen discloses the limitation as discussed in Claim 5 above. Umen further discloses

generating creates a customized database that is in conformance with the set of rules and the at

least one answer (col 10, lines 45-68).

Referring to Claim 7:

Umen discloses the limitation as discussed in Claim 1 above. Umen further discloses the

providing a user with at least one question, the receiving at least one answer, the retrieving a set

of rules, the analyzing, and the generating are all performed on a common Web site (col 4, lines

20-55).

Referring to Claim 8:

Umen discloses a creation system for generating a customized database management

system, the creation system comprising:

a computer configured to execute a first routine for asking a user at least one question related to a desired application for the customized database management system and for receiving at least one answer to the at least one question from the user (Fig 3; col 6, lines 10-25);

the computer further configured to execute a second routine for retrieving a set of rules associated with the desired application for the customized database management system (col 6, line 50-col 7, line 15);

the computer further configured to execute a third routine for processing an analysis of the at least one answer and the set of rules (col 2, lines 25-68; col 10, lines 45-55); and

the computer further configured to execute a fourth routine for generating the customized relational database management system according to the analysis (col 10, lines 45-55);).

Umen does not disclose the claimed "customized database".

Microsoft's Computer dictionary defines a document to be any self-contained piece of work created with an application program and, if saved on disk, given a unique filename by which it can be retrieved. Documents are generally thought of as word-processed materials only. To a computer, however, data is nothing more that a collection of characters, so a spreadsheet or a graphic is as much a document as is a letter or report. Therefore a document and the claimed customized database are equivalent.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the teachings of Umen to generate the claimed customized database/document. One of ordinary skill in the art would have been motivated to do this because it would provide a database that is in compliance with FDA clinical trials regulatory rules (col 2, lines 55-65).

Referring to Claim 9:

Umen discloses the limitation as discussed in Claim 8 above. Umen further discloses the

customized database management system is a clinical trials database management system (col 4,

lines 55-65).

Referring to Claim 10:

Umen discloses the limitation as discussed in Claim 8 above. Umen further discloses the

desired application is a clinical trial (col 4, lines 55-65).

Referring to Claim 11:

Umen discloses the limitation as discussed in Claim 10 above. Umen further discloses

the set of rules is in conformance with clinical trials regulations (col 2, lines 25-68; col 10, lines

45-55).

Referring to Claim 12:

Umen discloses the limitation as discussed in Claim 10 above. Umen further discloses a

generated customized database management system is in conformance with the set of rules and

the at least one answer (col 2, lines 25-68; col 10, lines 45-55; col 9, line 60-col 10, line 30).

Referring to Claim 13:

Umen discloses the limitation as discussed in Claim 9 above. Umen further discloses the

asking and receiving are handled by a dialogue box described by software executed by the

computer (col 5, lines 10-20).

Referring to Claim 14:

Umen discloses the limitation as discussed in Claim 9 above. Umen further discloses the

first routine, second routine, third routine, and fourth routine reside at a common Web site (col 4,

lines 20-55).

Referring to Claim 15:

Umen discloses a method for creating a clinical trials database management system, the

method comprising:

provides information descriptive of a particular clinical trial (Fig 3; col 6, lines 10-25);

providing a first set of rules in accordance with clinical trials governing regulations (col

2, lines 25-68; col 10, lines 45-55);

generating a second set of rules that conforms to the information and to the first set of

rules (col 9, line 60-col 10, line 15); and

generating the clinical trials database management system to be compliant with the

second set of rules (col 10, lines 45-60).

Umen does not disclose the claimed "customized database".

Microsoft's Computer dictionary defines a document to be any self-contained piece of work created with an application program and, if saved on disk, given a unique filename by which it can be retrieved. Documents are generally thought of as word-processed materials only. To a computer, however, data is nothing more that a collection of characters, so a spreadsheet or a graphic is as much a document as is a letter or report. Therefore a document and the claimed customized database are equivalent.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the teachings of Umen to generate the claimed customized database/document. One of ordinary skill in the art would have been motivated to do this because it would provide a database that is in compliance with FDA clinical trials regulatory rules (col 2, lines 55-65).

Referring to Claim 16:

Umen discloses the limitation as discussed in Claim 15 above. Umen further discloses the clinical trials database management system is contained within a Web site (col 4, lines 20-55).

Referring to Claim 17:

Umen discloses the limitation as discussed in Claim 16 above. Umen further discloses the clinical trials database management system is operable on the Web site (col 4, lines 20-55).

Referring to Claim 18:

Umen discloses the limitation as discussed in Claim 15 above. Umen further discloses the information descriptive of a particular clinical trial includes a user name, and data collection specifications (col 6, lines 10-20).

Referring to Claim 19:

Umen discloses the limitation as discussed in Claim 18 above. Umen further discloses the information descriptive of a particular clinical trial further includes specifications for data cleaning (col 10, lines 45-60).

Final Rejection

5.   **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monplaisir G Hamilton whose telephone number is 1703-305-5116. The examiner can normally be reached on Monday - Friday (8:00 am - 4:30 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John E Breene can be reached on 1703-305-9790. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 1703-305-3900.

Monplaisir Hamilton

JEAN M. CORRIELUS
PRIMARY EXAMINER